

MAY 16 2001

K003732

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## **510(k) Summary**

### **Company Information**

Braun GmbH  
Frankfurter Strasse 145  
D-61476 Kronberg  
Germany

### **Device Identification**

Trade Name – Braun PrecisionSensor™

Common Name – Wrist Blood Pressure Monitor

Classification Name – Noninvasive Blood Pressure Measurement System

Device Class – II

Product Code 74 DXN

### **Predicate Device**

Nihon Seimitsu Sokki Co., Ltd. Model WS-300 Automatic Digital Electronic Wrist Blood Pressure Monitor, K 981702, SE decision 03/05/1999

### **Device Description**

The Braun PrecisionSensor (BP2000 series) is a wrist blood pressure monitor that is battery powered. The monitor measures systolic and diastolic blood pressure, and pulse rate. The higher featured subtypes provide memory tracks of blood pressure and pulse rate readings that are time and date stamped. The BP2000 series wrist blood pressure monitor is intended for use in a home environment. The BP2000 series blood pressure monitor features an active positioning system. The active position system assists the user in positioning the monitor for repeatable blood pressure measurements. Therefore, positioning errors that contribute to inaccurate readings can be minimized. Once the BP2000 monitor is correctly positioned, the cuff automatically inflates and deflates. The user's systolic and diastolic blood pressure and pulse rate are displayed on the large, easy to read LCD.

### **Intended Use**

The Braun PrecisionSensor is intended for the noninvasive measurement of systolic and diastolic blood pressure and pulse rate, in adult populations.

### **Indications for Use**

The Braun PrecisionSensor is indicated for use in measuring blood pressure on the wrist, and for measuring pulse rate, in a home use environment.

### **Comparison with Predicate Device**

The Braun PrecisionSensor is substantially equivalent to the Nissei WS-300 Automatic Digital Electronic Wrist Blood Pressure Monitor that was cleared by FDA under K981702. For example both devices:

- are wrist blood pressure monitors,
- have the same intended use,
- have the same indications for use,
- have similar principals of operation,
- have similar operating ranges,
- have similar displays
- have similar power sources, and
- have similar environmental operating and storage conditions.

### **Performance Data**

Extensive internal and external laboratory testing has been conducted to verify and validate the performance of PrecisionSensor to both internal specifications and external standards.

- Laboratory performance testing demonstrated that the BP2000 monitor functions to internal specifications that are inclusive of international standards such as EN 1060-1, -3.
- Safety performance testing included test results that demonstrate conformance with the requirements of biocompatibility and electromagnetic compatibility.
- Clinical performance testing included successful testing for conformance to the ANSI/AAMI National Standard SP-10 for Electronic or automated sphygmomanometers. Results demonstrated overall system accuracy in a general adult population across wide ranges of blood pressure, arm and wrist circumference, body mass, age, and concomitant diseases and medication that demonstrate overall system accuracy, and conformance to the requirements of this national standard.
- The risk analysis, performed in compliance with EN 1441, confirmed that the BP2000 monitor does not subject users to needless risks and that identified risks were mitigated or eliminated.

The individual and cumulative results of these tests demonstrate that the Braun PrecisionSensor (2000 Series) wrist blood pressure monitor:

- complies with internal specifications and external standards,
- is substantially equivalent to the Nissei Model WS-300 Automatic Digital Electronic Wrist Blood Pressure Monitor, and
- is a suitable device for measuring blood pressure on the wrist when used properly and according to the Instructions for Use.



MAY 16 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Braun GmbH  
c/o Mr. Fred Schlador  
Regulatory Resources, LLC  
6183 Paseo Del Norte, Suite 150  
Carlsbad, CA 92009

Re: K003732

Trade Name: Braun PrecisionSensor™ (BP2000 series) Wrist  
Blood Pressure Monitor  
Regulation Number: 870.1130  
Regulatory Class: II (two)  
Product Code: 74 DXN  
Dated: March 2, 2001  
Received: March 5, 2001

Dear Mr. Schlador:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

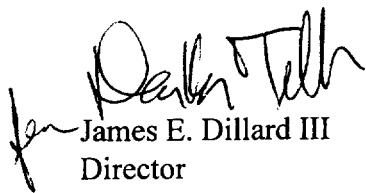
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the printed name.

James E. Dillard III

Director

Division of Cardiovascular  
and Respiratory Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): k003732

Device Name: PrecisionSensor™ wrist blood pressure monitor


Indications for Use:

The Braun PrecisionSensor™ (BP2000 series) wrist blood pressure monitor is indicated for use for the noninvasive measurement of blood pressure (systolic and diastolic) and pulse rate in adults, in a home use setting. Use may be initiated by the individual or as part of a hypertension monitoring and management program supervised by a health care provider.

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PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number k003732

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over the Counter ✓